



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
-----------------	-------------	----------------------	---------------------	------------------

10/645,823

08/21/2003

Joseph M. Pastore

279.606US1

7664

21186 7590 03/08/2007

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.

P.O. BOX 2938

MINNEAPOLIS, MN 55402

EXAMINER

WILLIAMS, CATHERINE SERKE

ART UNIT

PAPER NUMBER

3763

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
--	-----------	---------------

3 MONTHS

03/08/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/645,823

Applicant(s)

PASTORE ET AL.

Examiner

Catherine S. Williams

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-78 is/are pending in the application.
- 4a) Of the above claim(s) 1-17,33-35,38-55,67-69,73 and 74 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-32,36,37,56-66,70-72 and 75-78 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date all.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of species 3 (figures 6-8) in the reply filed on 12/12/06 is acknowledged. The traversal is on the ground(s) that a search for species 3 (figures 6-8) would result in finding prior art for species 2 (figures 4-5). This is not found persuasive because the species are not taught as obvious variants of one another. A restriction is proper if the species are patently distinct inventions. If applicant believes that these species are not patently distinct then please indicate that they are obvious variants of one another and the restriction requirement between species 2 and 3 will be removed.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17,33-35,38-55 and 73-74 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/12/06.

Additionally, claims 67-69 seem to be directed to a nonelected species. Therefore, these claims are being withdrawn.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18-23,26,36-37,56-58,61,66,70-71 and 75-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (USPN 4,146,029) in view of Lopaschuk et al (USPN 6,693,133). Ellinwood discloses an implanted programmable medication system and method that includes an implantable metabolic sensor (60) that can sense pH or glucose among other factors, an implantable processor (61; see also 17:13-22) and an implantable drug delivery device (59,62). See figure 4. It is considered inherent that the processor will include circuitry and a controller. These are considered necessary for the device to perform as disclosed in the reference.

Ellinwood meets the claim limitations as described above but fails to include a drug that shifts a source of metabolically synthesized energy for cardiac contractions from fatty acid to glucose. However, Lopaschuk discloses such a drug.

At the time of the invention, it would have been obvious to incorporate the drug as taught by Lopaschuk into the drug delivery system of Ellinwood. The motivation for the incorporation can be found in Lopaschuk in that the delivery means is not limited to one particular method. See 8:33+. Additionally, the device of Ellinwood has particular use in monitoring of cardiac function and delivery of cardiac drugs.

Art Unit: 3763

Claims 24-25,27-30,59-60 and 62-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (USPN 4,146,029) in view of Lopaschuk et al (USPN 6,693,133). Ellinwood in view of Lopaschuk meet the claim limitations as described above but fail to include the particular sensors of claims 24-25,27-30.

At the time of the invention, it would have been an obvious design choice to substitute any or all of the claimed sensors into the invention of Ellinwood in view of Lopaschuk. Applicant has failed to present that these particular sensors in comparison to the pH or glucose sensors provides an advantage, is used for a particular purpose or solves a problem. Furthermore, one would expect the pH, glucose or any of the claimed sensors to perform equally well in providing cardiac functioning/metabolic information to the device/user.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (USPN 4,146,029) in view of Lopaschuk et al (USPN 6,693,133) in further view of Barrerras, Sr. et al (USPN 5,733,313). Ellinwood in view of Lopaschuk meet the claim limitations as described above but fail to include a reservoir drug level detector. However, Barrerras discloses such a detector. See 10:59+.

At the time of the invention, it would have been obvious to incorporate a drug level detector as taught by Barrerras into the invention of Ellinwood in view of Lopaschuk. The motivation for the incorporation would have been known commonly in the art in that a drug level detector would enhance the safety of the device to the patient.

Art Unit: 3763

Claims 32 and 72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ellinwood, Jr. (USPN 4,146,029) in view of Lopaschuk et al (USPN 6,693,133) in further view of (USPN 6,824,561 or 6,802,811 or 6,206,914). Ellinwood in view of Lopaschuk meet the claim limitations as described above but fail to include a stent delivery device. However, each of these three patents teach the use of drug eluding stents for cardiac drug delivery applications.

At the time of the invention, it would have been obvious to incorporate the use of a stent as taught by the three above patents into the invention of Ellinwood in view of Lopaschuk. The motivation for the incorporation would have been in that the delivery device by Ellinwood was not specified to a particular mechanism and drug eluding stents are commonly known in the art and would enhance the performance of the device of Ellinwood.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Catherine S. Williams whose telephone number is 571/2724970. The examiner can normally be reached on Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nicholas D. Lucchesi can be reached on 571/2724977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3763

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Catherine S. Williams
March 1, 2007

CATHERINE S. WILLIAMS
PRIMARY EXAMINER